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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------------------------------------------------------------|-------------|----------------------|---------------------|------------------|
| 09/890,425 | 02/19/2002 | Harold G. Brown | 2059-0103P | 1812 |
| 2292 | 7590 | 01/25/2008 | EXAMINER | |
| BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747 | | | UNDERDAHL, THANE E | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1651 | |
| | | | NOTIFICATION DATE | DELIVERY MODE |
| | | | 01/25/2008 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailto:mailroom@bskb.com

| | | |
|------------------------------|------------------------------------|-------------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/890,425 | BROWN ET AL. |
| | Examiner Thane Underdahl | Art Unit 1651 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 1/11/08.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) 24-27,30,32-35,52,97-111 and 116 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) See Continuation Sheet is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date 1/11/08.
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application
- 6) Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 7,8,11,12,14,19,22-27,30,32-37,41,42,46-48,51-54,59,66,69,70,72-94 and 97-128.

Continuation of Disposition of Claims: Claims rejected are 7,11,12,14,19,22,23,36,37,41,42,46-48,51,53,54,59,66,69,70,72-94,112-115 and 117-128.

DETAILED ACTION

This Office Action is in response to the Applicant's reply received 10/24/07. Claims 7, 8 11, 12, 14, 19, 22, 23, 24-27, 30, 32-35, 36, 37, 41, 42, 46-48, 51, 52, 53, 54, 59, 66, 69, 70, 72-94, 97-111, 112-115, 116, 117-127, 128 are pending. Claims 24-27, 30, 32-35, 52, 97-111, 116 are withdrawn.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/24/07 has been entered.

Response to Applicant's Arguments— 35 U.S.C § 102 and 103

In the response submitted by the Applicant all of the 35 U.S.C § 102(b) and 103 (a) rejections of claims 7, 9, 11, 12, 14, 19, 22, 23, 36, 37, 41, 42, 46-48, 51, 53, 54, 59, 66, 69, 70, 72-90, 91-94, 112, 113, 115, and 117-127 based on Turley et al. and numerous supporting references are withdrawn in light of applicant's amendment combined with the Rule 132 Affidavit submitted on 7/25/07.

New Rejections Necessitated by Amendment

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7, 11, 12, 14, 19, 22, 23, 36, 37, 41, 42, 46-48, 51, 53, 54, 59, 66, 69, 70, 72-90, 91-94, 112, 113, 114, 115, and 117-128 are rejected under 35 U.S.C. 103(a) as being unpatentable over Della Valle et al. (U.S. Patent # 4736024) and further in view of Balazs (U.S. Patent # 4,141973).

These claims are to a composition of orally ingestible or mucosally absorbable glycosaminoglycan such as hyaluronic acid (hyaluronan or HA) that has at least one fraction with a molecular weight 1,000,000 daltons as measure by the protein standard/intrinsic viscosity. The composition must not contain an essential oil as an active ingredient and contains up to 5% by weight protein contaminants and a carrier selected from several forms such as a vaporizer liquid, spray, cream, ointment, drink or drink mix. The composition may also contain a second glycosaminoglycan fraction from weighing from 1,000 to less than 50,000 daltons and 100,000 to 300,000 daltons. The composition contains less than 98% HA.

Claims 54, 113 and 123 recite an intended use and a method step for their respective compositions. These intended uses do not impart a structural relationship, such as an additional component, to the composition (M.P.E.P. § 2111.02 II). Since compositions are defined and limited by their components, these limitations are not further limiting.

Della Valle et al. teach a composition that may have fractions of HA from ~11 million to 30,000 (Della Valle, col 6, lines 1-10) for applications in human and veterinary medicine (Della Valle, col 2, lines 57-60) that is absent and essential oil as the active ingredient. This composition can be formulated into preparation for adsorption through the mucus membranes (Della Valle, col 5, lines 3-5) such as nasal sprays or oral inhalers or even gels and ointments with, pain-reliever (analgesic) anti-biotic and anti-inflammatory properties (Della Valle, col 3 and 4, entire section, specifically col 3, lines 25-35 and Examples 1-19). Since the HA can be applied orally or nasally it would have been obvious to someone skilled in the art that that HA is of at least food grade purity. Della Valle lists multiple ranges for the HA in their composition from 13 million to 30,000 as well as 50,000 to about 100,000. The amount of HA in their many compositions can vary greatly with some examples showing 34.0% and 80.0% HA (Della Valle, Example 2 and 5).

What Della Valle et al. does not teach is that the HA is defined by its intrinsic viscosity or by the protein standard. Regardless this would be obvious to one of ordinary skill in the art by the time the invention was made in view of the teachings of Balazs. He teach an ultrapure HA that can be made into a 1% optomological solution and does not cause the inflammation of owl monkey eyes (Balazs, see Abstract). His ultrapure solution of HA has a molecular weight of greater than 1,200,000 as measure by intrinsic viscosity (Balaz, col 4, lines 40-50). The HA of Balazs also contains a protein content of less then 0.5% by weight.

It would have been obvious to someone skilled in the art to use the HA of Balazs in the compositions of Della Valle et al. A *prima facie* case can be made since Della Valle et al. directly cites this same patent in their patent (Della Valle et al., see References Cited). Also Della Valle et al. expressly mentions the work of Balazs on the isolation and use of HA in the specification of their patent (Della Valle et al., col 5, lines 15-45). Therefore one of ordinary skill in the art would be motivated and have a reasonable expectation of success to use the HA of Balazs in the invention of Della Valle et al. Also one of ordinary skill in the art would be motivated to measure their other shorter chain fractions of HA by intrinsic viscosity to make sure they have a common standard of molecular weight between the large and small fractions. Since both Balazs and Della Valle et al. teach the use of HA in the similar molecular weight range it would have been obvious to someone skilled in the art to use the HA characterized by intrinsic viscosity of Balazs in the invention of Della Valle et al since one of ordinary skill in the art would recognize these are art-defined equivalents for the same purpose and have the same predictable result. (M.P.E.P. § 2144.06 and *KSR International Co. v. Teleflex Inc.*, 550 U.S.--, 82 USPQ2d 1385 (2007)).

Also while neither Della Valle and Balazs teach the multiple formulations listed in claims 74-88 such as a gargle, gum, lozenge, foam or capsule they have already taught that the HA compositions are safe for oral, eye and topical application. It would have been obvious to someone skilled in the art to alter their product into these formulations since these are simply well known variations on the formulation for oral and topical administration of compositions.

Therefore the references listed above renders obvious claims 7, 11, 12, 14, 19, 22, 23, 36, 37, 41, 42, 46-48, 51, 53, 54, 59, 66, 69, 70, 72-90, 91-94, 112, 113, 114, 115, and 117-128.

In summary no claims, as written, are allowed for this application.

In response to this office action the applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

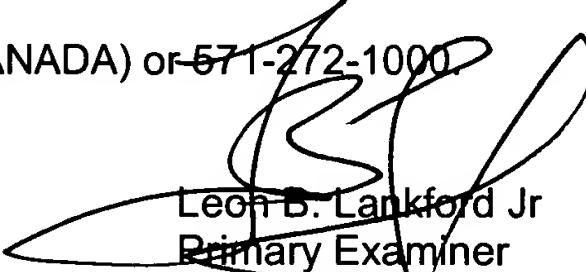
CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571) 272-9042. The examiner can normally be reached Monday through Thursday, 8:00 to 17:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Thane Underdahl
Art Unit 1651


Leon B. Lankford Jr
Primary Examiner
Art Unit 1651